

T. Osypka
U.S. Serial No. 10/625,175
Page 2 of 13

Amendments to the claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

Claim 1 (currently amended): A bipolar cardiac lead, comprising:

a)-an elongated lead body having opposed proximal and distal end portions, and defining a longitudinal axis;

b)-an electrode housing operatively associated with the distal end portion of the lead body for stimulating cardiac tissue;

a conductor coil extending through a lumen in the elongated lead body, the conductor coil being electrically connected to at least a connective portion of the electrode housing; and

e)-a helical fixation screw disposed within the electrode housing along an axis extending generally perpendicular to the longitudinal axis of the lead body and mounted for movement between an axially retracted position and an axially extended position ~~to affix~~for affixing the electrode housing to the cardiac tissue, wherein ~~at least a portion of the~~ helical fixation screw is electrically active ~~connected to the connective portion of the electrode housing; and~~

an insulating tube positioned radially outside of the helical fixation screw in the electrode housing for eluting at least one drug.

Claim 2 (currently amended): The bipolar cardiac lead as recited in claim 1, further including an internally threaded collar and an externally threaded plug disposed within the electrode housing, wherein the helical fixation screw depends from ~~an~~the externally threaded plug supported within ~~an~~the internally threaded collar ~~disposed within the electrode housing.~~

Claim 3 (currently amended): The bipolar cardiac lead as recited in claim 2, further including a screwdriver tipped stylet extended into the electrode housing and a self-sealing opening formed in the electrode housing, wherein the externally threaded plug is configured for engagement with

T. Osypka
U.S. Serial No. 10/625,175
Page 3 of 13

~~a the~~ screwdriver tipped stylet extended into the electrode housing through ~~a the~~ self-sealing opening ~~formed in the electrode housing~~.

Claim 4 (original): The bipolar cardiac lead as recited in claim 3, wherein the screwdriver tipped stylet is positioned outside the lead body.

Claim 5 (original): The bipolar cardiac lead as recited in claim 3, further including a flexible guiding sheath positioned outside the lead body to accommodate the screwdriver tipped stylet.

Claim 6 (original): The bipolar cardiac lead as recited in claim 5, wherein the guiding sheath has at least one bendable section.

Claim 7 (original): The bipolar cardiac lead as recited in claim 1, wherein the electrode housing includes a ring electrode.

Claim 8 (currently amended): The bipolar cardiac lead as recited in claim 7, ~~further including~~ ~~anywherein the~~ insulating tube is coaxially disposed within the ring electrode.

Claim 9 (original): The bipolar cardiac lead as recited in claim 8, wherein the insulating tube is formed from a compound including an elastomer and a medicament.

Claim 10 (original): The bipolar cardiac lead as recited in claim 9, wherein the compound from which the insulating tube is formed includes silicone and a steroid.

Claim 11 (original): The bipolar cardiac lead as recited in claim 10, wherein the compound from which the insulating tube is formed has a durometer of about 40 to 90 Shore A.

Claim 12 (original): The bipolar cardiac lead as recited in claim 10, wherein the compound from which the insulating tube is formed includes about 15% to 25% by weight steroid.

T. Osypka
U.S. Serial No. 10/625,175
Page 4 of 13

Claim 13 (currently amended): The bipolar cardiac lead as recited in claim 7, wherein the ring electrode ~~serves-is adapted to serve~~ as an anode and a tip portion of the helical fixation screw ~~serves-is adapted to serve~~ as a cathode.

Claim 14 (currently amended): The bipolar cardiac lead as recited in claim 7, wherein the ring electrode and a proximal portion of the helical fixation screw ~~serve-are adapted to serve~~ as an anode, and a tip portion of the helical fixation screw ~~serves-is adapted to serve~~ as a cathode.

Claim 15 (original): The bipolar cardiac lead as recited in claim 14, wherein the helical fixation screw further includes an insulator separating the proximal portion from the tip portion of the helical fixation screw.

Claim 16 (currently amended): The bipolar cardiac lead as recited in claim 1, wherein in the axially extended position, the helical fixation screw ~~penetrates-is adapted to penetrate~~ into heart tissue a length of up to about 10 mm.

Claim 17 (currently amended): The bipolar cardiac lead as recited in claim 1, wherein in the axially extended position, the helical fixation screw ~~penetrates-is adapted to penetrate~~ into heart tissue a length of about 3 mm to 10 mm.

Claim 18 (original): The bipolar cardiac lead as recited in claim 1, further including a needle-shaped fixation pin positioned within the helical fixation screw.

Claim 19 (original): The bipolar cardiac lead as recited in claim 18, wherein the length of the helical fixation screw is about 7 mm to 10 mm, and the length of the fixation pin is about 5 mm to 7 mm.

Claim 20 (original): The bipolar cardiac lead as recited in claim 1, wherein the lead body contains at least one conductor coil.

T. Osypka
U.S. Serial No. 10/625,175
Page 5 of 13

Claim 21 (original): The bipolar cardiac lead as recited in claim 20, further including an insulating sheath of biocompatible material covering the at least one conductor coil.

Claim 22 (original): The bipolar cardiac lead as recited in claim 1, further including a connector operatively associated with the proximal end of the lead body.

Claim 23 (currently amended): A bipolar cardiac lead, comprising:

a) an elongated lead body having opposed proximal and distal end portions, and defining a longitudinal axis;

b) an electrode housing operatively associated with the distal end portion of the lead body, the electrode housing including a ring electrode for stimulating cardiac tissue; and

c) a helical fixation screw disposed within the electrode housing along an axis extending generally perpendicular to the longitudinal axis of the lead body and mounted for movement between an axially retracted position and an axially extended position ~~to affix~~ for affixing the electrode housing to the cardiac tissue, wherein the helical fixation screw depends from an externally threaded plug supported within an internally threaded collar disposed within the electrode housing[.];

an insulating tube positioned radially outside of the helical fixation screw in the electrode housing for eluting at least one drug; and

the externally threaded plug configured for engagement with a screwdriver tipped stylet extended into the electrode housing and configured for engagement with the externally threaded plug.

Claim 24 (original): The bipolar cardiac lead as recited in claim 23, wherein the screwdriver tipped stylet is positioned outside the lead body.

Claim 25 (original): The bipolar cardiac lead as recited in claim 23, further including a flexible guiding sheath positioned outside the lead body to accommodate the screwdriver tipped stylet.

T. Osypka
U.S. Serial No. 10/625,175
Page 6 of 13

Claim 26 (currently amended): The bipolar cardiac lead as recited in claim 23, ~~further including~~
~~an wherein the~~ insulating tube is coaxially disposed within the ring electrode.

Claim 27 (original): The bipolar cardiac lead as recited in claim 26, wherein the insulating tube is formed from a compound comprising an elastomer and a medicament.

Claim 28 (original): The bipolar cardiac lead as recited in claim 27, wherein the compound from which the insulating tube is formed includes silicone and a steroid.

Claim 29 (original): The bipolar cardiac lead as recited in claim 28, wherein the compound from which the insulating tube is formed has a durometer of about 40 to 90 Shore A.

Claim 30 (original): The bipolar cardiac lead as recited in claim 28, wherein the compound from which the insulating tube is formed includes about 15% to 25% by weight steroid.

Claim 31 (original): The bipolar cardiac lead as recited in claim 23, wherein the helical fixation screw includes a proximal portion and a distal portion terminating in a tip portion.

Claim 32 (currently amended): The bipolar cardiac lead as recited in claim 31, wherein the ring electrode ~~serves is adapted to serve~~ as an anode and the tip portion of the helical fixation screw ~~serves is adapted to serve~~ as a cathode.

Claim 33 (currently amended): The bipolar cardiac lead as recited in claim 31, wherein the ring electrode and the proximal portion of the helical fixation screw are adapted to serve as an anode, and the tip portion ~~serves is adapted to serve~~ as a cathode.

Claim 34 (original): The bipolar cardiac lead as recited in claim 33, wherein the helical fixation screw further includes an insulator separating the proximal portion from the tip portion of the helical fixation screw.

T. Osypka
U.S. Serial No. 10/625,175
Page 7 of 13

Claim 35 (original): The bipolar cardiac lead as recited in claim 23, wherein a self-sealing opening is formed in the electrode housing for receiving the screwdriver tipped stylet.

Claim 36 (currently amended): A cardiac lead implantation kit, comprising:

a) a bipolar cardiac lead including:

i) an elongated lead body having opposed proximal and distal end portions, and defining a longitudinal axis;

ii) an electrode housing operatively associated with the distal end portion of the lead body for stimulating cardiac tissue; and

iii) a helical fixation screw disposed within the electrode housing along an axis extending generally perpendicular to the longitudinal axis of the lead body and mounted for movement between an axially retracted position and an axially extended position to ~~affix~~ for affixing the electrode housing to the cardiac tissue; and

an insulating tube positioned radially outside of the helical fixation screw in the electrode housing for cluting at least one drug;

b) a screwdriver tipped stylet for facilitating movement of the helical fixation screw; and

c) a flexible guide sheath for directing the tip of the stylet to the electrode housing.

Claim 37 (original): The cardiac lead implantation kit as recited in claim 36, wherein a self-sealing opening is formed in the electrode housing for receiving the screwdriver tipped stylet.

Claim 38 (original): The cardiac lead implantation kit as recited in claim 37, wherein the electrode housing includes a ring electrode.

Claim 39 (original): The cardiac lead implantation kit as recited in claim 38, further including an insulating tube coaxially disposed within the ring electrode.

Claim 40 (original): The cardiac lead implantation kit as recited in claim 39, wherein the insulating tube is formed from a compound comprising an elastomer and a medicament.

T. Osypka
U.S. Serial No. 10/625,175
Page 8 of 13

Claim 41 (original): The cardiac lead implantation kit as recited in claim 40, wherein the compound from which the insulating tube is formed includes silicone and a steroid.

Claim 42 (original): The cardiac lead implantation kit as recited in claim 41, wherein the compound from which the insulating tube is formed has a durometer of about 40 to 90 Shore A.

Claim 43 (original): The cardiac lead implantation kit as recited in claim 41, wherein the compound from which the insulating tube is formed includes about 15% to 25% by weight steroid.

Claim 44 (currently amended): The cardiac lead implantation kit as recited in claim 37, wherein the ring electrode ~~serves~~ is adapted to serve as an anode and a tip portion of the helical fixation screw ~~serves~~ is adapted to serve as a cathode.

Claim 45 (original): The cardiac lead implantation kit as recited in claim 44, wherein the helical fixation screw further includes an insulator separating the ring electrode from the tip portion of the helical fixation screw.

Claim 46 (currently amended): The cardiac lead implantation kit as recited in claim 37, wherein the ring electrode and a proximal portion of the helical fixation screw are adapted to serve as an anode, and a tip portion of the helical fixation screw ~~serves~~ is adapted to serve as a cathode.

Claim 47 (original): The cardiac lead implantation kit as recited in claim 46, wherein the helical fixation screw further includes an insulator separating the proximal portion from the tip portion of the helical fixation screw.